No. 15-7

IN THE
Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC.,
Petitioner,

v.

UNITED STATES AND
COMMONWEALTH OF MASSACHUSETTS
EX REL. JULIO ESCOBAR AND CARMEN CORREA,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF PROFESSOR DAVID FREEMAN ENGSTROM AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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March 3, 2016

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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INTEREST OF *AMICUS CURIAE*[1]

Amicus is Professor of Law and Bernard D. Bergreen Faculty Scholar at Stanford Law School where he teaches and writes in the areas of civil procedure, administrative law, and empirical legal studies. *Amicus* has a longstanding academic interest in the False Claims Act (FCA), having recently completed the most comprehensive and rigorous empirical study of the FCA's workings. For this project, *amicus* built an extensive dataset encompassing more than 6,000 unsealed *qui tam* lawsuits filed under the FCA between 1986 and 2013. That work yielded numerous articles and book chapters, including a trio of empirical analyses of discrete aspects of the regime. *See* David Freeman Engstrom, *Private Enforcement's Pathways: Lessons from Qui Tam Litigation*, 114 Colum. L. Rev. 1913 (2014); David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 Nw. U. L. Rev. 1689 (2013); David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 Colum. L. Rev. 1244 (2012). *Amicus* also published a more general study of the legal and policy implications of vesting agencies with "litigation gatekeeper" authority across a range of regulatory contexts, including the FCA. *See* David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616 (2013).

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* represents that he authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than *amicus*, made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.3(a), *amicus* represents that the parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

Data, not anecdote, help frame the legal issues in this case. Petitioner and supporting *amici* offer mostly the latter by focusing this Court's attention on a limited but colorful set of outlier *qui tam* cases. This brief, in contrast, offers a data-based view by synthesizing relevant findings from a comprehensive and rigorous empirical study of more than 6,000 *qui tam* lawsuits filed under the False Claims Act (FCA) between 1986 and 2013.

The data unmistakably establish two points. First, the growth of *qui tam* litigation in recent decades is best characterized as a steady and stable process of maturation—not, as petitioner and supporting *amici* would have it, a "skyrocketing" increase or the output of a litigation "monster." Second, the United States Department of Justice (DOJ) has exercised firm, steady, and merits-focused control over *qui tam* litigation via its statutory authority to intervene in and take over control of *qui tam* actions and, in extreme cases, dismiss them out from under relators entirely. Importantly, simple DOJ declination has proven to be a powerful tool of control: In cases where DOJ declines to intervene but does not use its full dismissal power, the overwhelming majority of relators either fail to prosecute or else voluntarily dismiss their actions after no or only very limited litigation. On both points, empirical reality departs substantially from the anecdotal, and often alarmist, account of the FCA's workings offered by petitioner and supporting *amici*.

Taken together, these empirical findings fuel a further, critically important conclusion: DOJ's expert, case-by-case exercise of its statutory gatekeeper powers, backed where necessary by prudent judicial policing of the FCA's materiality and scienter provisions,

is most consistent with Congress's effort to craft a carefully balanced hybrid of public and private enforcement. By contrast, petitioner proposes bright-line, judicially devised rules that would foreclose or severely limit implied certification claims—even where DOJ, the contracting agency, and simple common sense support the case. That blunt approach is incompatible with Congress's chosen design.

ARGUMENT

I. *QUI TAM* LITIGATION UNDER THE FALSE CLAIMS ACT HAS STEADILY MATURED SINCE 1986; IN NO RELEVANT STATISTICAL SENSE CAN THE REGIME'S GROWTH BE CHARACTERIZED, AS PETITIONER AND SUPPORTING *AMICI* SUGGEST, AS A "SKYROCKETING" RISE OR THE OUTPUT OF A LITIGATION "MONSTER"

Since Congress substantially amended the False Claims Act (FCA) in 1986, *qui tam* litigation has grown from a trickle of filings to some 600 lawsuits and roughly $3 billion in recoveries per year.[2] For petitioner and supporting *amici*, the FCA regime has "wildly expanded" and "exploded," yielding a "deluge of litigation" and a "staggering boom."[3] They further assert that the "implied certification" claim at issue in

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[2] Annual aggregated data on *qui tam* filings and recoveries from 1986 to 2015 can be found at U.S. Dep't of Justice, *Fraud Statistics – Overview* (2015), http://www.justice.gov/opa/file/796866/download.

[3] *See* Brief of Amici Curiae American Medical Association et al. in Support of Petitioner 11; Brief of CTIA—The Wireless Association as Amicus Curiae in Support of Petitioner 15-16; Brief of Pharmaceutical Research and Manufacturers of America et al. as Amici Curiae in Support of Petitioner 20.

this case is a "Frankenstein's monster," Pet. Br. 2, and that *qui tam*'s growth can be attributed to the profusion of such claims, *see, e.g.*, Brief for Chamber of Commerce et al. as Amici Curiae in Support of Petitioner 34 ("The skyrocketing number of FCA lawsuits in recent years underscores the need to reject (or at least constrain) the implied-certification theory.").

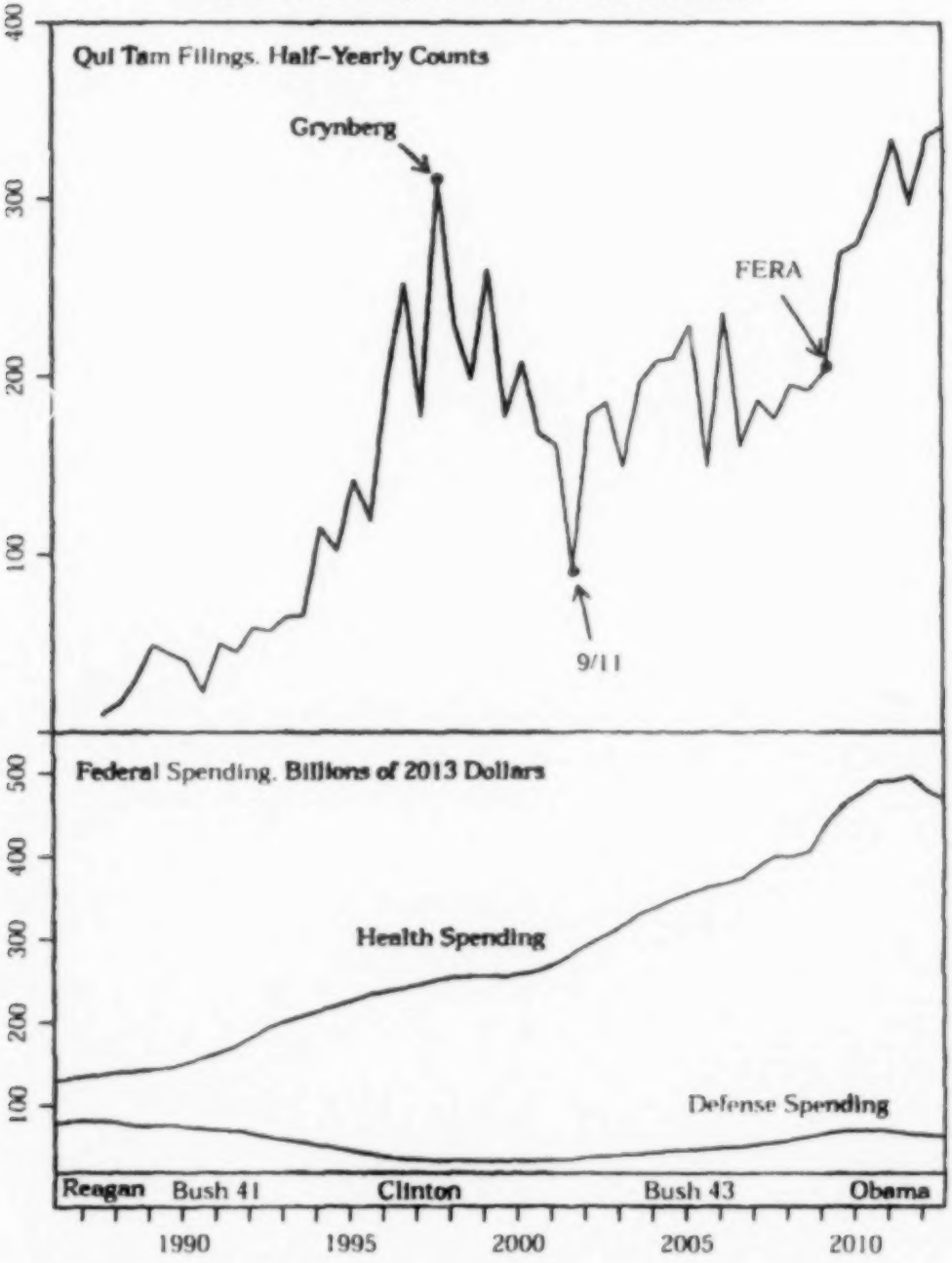
The data, however, point decisively away from such assertions. Indeed, empirical analysis of the regime's primary outputs—filings and recoveries—show that the FCA regime's growth is best characterized as a steady and stable process of maturation, not an explosion or the output of a litigation "monster." Importantly, there is no evidence that the advent of implied certification claims during a period spanning the mid-1990s to the late 2000s in any way altered observed trends.

A. Filings

Figure 1 presents half-yearly filing counts alongside some plausible explanations for the observed growth trends.[4] The data plots permit two key observations.

[4] A version of Figure 1 and further analysis of *qui tam* filing trends can be found in Engstrom, *Pathways*, *supra*, at 1952.

FIGURE 1. *QUI TAM* FILING TRENDS AND POSSIBLE EXPLANATIONS, 1986 TO JUNE 2013



First, *qui tam* filings remained flat or even declined between roughly 1996 and 2009—the time span during which implied certification claims first arose and, more importantly, earned judicial sanction in multiple

circuits.[5] To be sure, filing counts over this period show substantial variability. As flagged in Figure 1, filings reached a peak in 1997 when a single relator ("Grynberg") filed dozens of separate *qui tam* actions against the entire oil and gas industry.[6] Filings plummeted in the immediate aftermath of the September 11th terrorist attacks. Still, the key point remains: The advent of implied certification claims from the mid-1990s to the late 2000s did not produce an obvious uptick, let alone an explosive one, in *qui tam* litigation efforts.

Second, Figure 1 helps to characterize the FCA's modern evolution by highlighting a pair of far more plausible explanations for the regime's long-run growth than the advent of implied certification claims. One is congressional action: The two most dramatic periods of growth in *qui tam* filings coincide with congressional amendments—first in 1986, when Congress revived a moribund FCA with strengthening

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[5] *See, e.g.*, *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *United States v. TDC Mgmt. Corp.*, 288 F.3d 421, 426 (D.C. Cir. 2002); *Ab-Tech Constr., Inc. v. United States*, 57 F.3d 1084 (Fed. Cir. 1995), *aff'g* 31 Fed. Cl. 429, 434 (1994). Several circuits also refused to accept or reject implied certification claims during this period, in theory inviting filings. *See, e.g.*, *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1172-73 & n.1, 1177 (9th Cir. 2006) (declining to address the implied certification theory, but also appearing to reject a condition-of-payment limitation on FCA liability); *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 382 (5th Cir. 2003) (declining to bless implied certification but implying that, in any event, they would be subject to a condition-of-payment requirement); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 n.8 (4th Cir. 1999) (calling implied certification "questionable" in dicta but declining to accept or reject the theory).

[6] *See, e.g.*, *United States ex rel. Grynberg v. Exxon Pipeline Co.*, No. 97-198B (D. Wyo. filed Aug. 6, 1997).

amendments, and then again in 2009, when Congress broadened and strengthened the FCA via the Fraud Enforcement and Recovery Act (FERA).[7]

A second explanation—though one that is hard to test empirically because of the well-known challenges of time-series analysis[8]—is simple growth in the types of government spending that are the most frequent subject of *qui tam* lawsuits. As Figure 1's bottom stack shows, federal health and defense-procurement expenditures—which can be thought of as the bulk of "fraud-eligible" federal funds in a *qui tam* system dominated by health- and defense-related claims—have more than doubled in real-dollar terms since 1986 and saw particularly rapid growth throughout the 2000s, due in part to a new prescription-drug entitlement under Medicare and a post-9/11 rise in defense spending. In short, it is congressional action and increases in government health and defense spending, not judicial rulings regarding implied certification claims, that appear to have had the greatest impact on *qui tam*'s growth over time.

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[7] Pub. L. No. 111-21, 123 Stat. 1617 (2009). As detailed below (at 26), Congress enacted FERA to broaden the coverage of the FCA, in large part by abrogating "judicially-created limitations and qualifications" that restricted liability for claims submitted by subcontractors to contractors rather than the government itself; claims submitted to funds administered but not owned by the government, including the Iraq Coalition Provisional Authority; and so-called "reverse false claims" (*i.e.*, knowing retention of monies owed to the United States). *See* H.R. Rep. No. 111-97, at 2, 5-8 (2009) (detailing cases).

[8] Comparing two trending time series of the sort depicted in Figure 1 is vulnerable to spurious results because error terms are likely to autocorrelate. *See* C. W. J. Granger & P. Newbold, *Spurious Regressions in Econometrics*, 2 J. Econometrics 111, 117-19 (1974).

This conclusion finds further support in circuit-specific *qui tam* filing counts. Perhaps the best—if imperfect—test in this regard is to compare filing trends before and after a cluster of court-of-appeals opinions variously blessing and restricting implied certification claims during the early to mid-2000s.[9] Performing such an analysis finds no evident relationship between these rulings and *qui tam* filing counts.

For instance, filings within the Second Circuit indeed *decreased*, from 43 to 38, during the three-year windows before and after the 2001 *Mikes* decision imposing a condition-of-payment requirement of the sort petitioner advocates in this case, *see* 274 F.3d at 700-02. But filings remained *flat* in the Sixth Circuit (82 to 84 filings) in the three-year windows before and after the 2002 *Augustine* decision appeared to embrace *Mikes* in adopting a condition-of-payment requirement, *see* 289 F.3d at 415. And filings in the Fifth Circuit substantially *increased* (73 to 101 filings) during the three years before and after the 2003 *Willard* decision, which declined to address the implied certification theory but noted that, in any event, the relator had failed to allege that the regulation was a condition of payment, *see* 336 F.3d at 382.

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[9] The cases used in the analysis that follows include: *Mikes v. Straus*, 274 F.3d 687, 700-02 (2d Cir. 2001) (sanctioning an implied certification theory but imposing a condition-of-payment requirement); *United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409, 415 (6th Cir. 2002) (same); *United States ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 382 (5th Cir. 2003) (declining to decide whether to recognize implied certification claims because, in any event, compliance with the regulations at issue were not an express condition of payment); *United States v. TDC Management Corp.*, 288 F.3d 421, 426 (D.C. Cir. 2002) (appearing to embrace implied certification claims and rejecting a *Mikes* restriction).

Turning to the other side of the circuit split in this case only further muddies matters: Filings *decreased* (27 versus 23) across the three-year spans before and after the D.C. Circuit's 2002 decision in *TDC Management*, which appeared to embrace implied certification claims and also reject a *Mikes* requirement in permitting a claim to go forward where defendant failed to disclose regulatory violations that were "contrary to Program terms" but not express conditions of payment, *see* 288 F.3d at 426. Here again, there is simply no warrant in the filings data to conclude that implied certification claims have significantly impacted the FCA's regime's growth over time.

B. Recoveries

Figure 2 (on the next page) offers a second window onto *qui tam*'s recent growth by focusing on recoveries.[10] The top stack plots all recoveries between 1986 and 2013, designating those above $100 million by way of an industry-specific letter designation rather than a dot. The bottom stack then offers a smoothed (LOWESS) curve of the annual mean and median recovery amounts across all cases producing a recovery.

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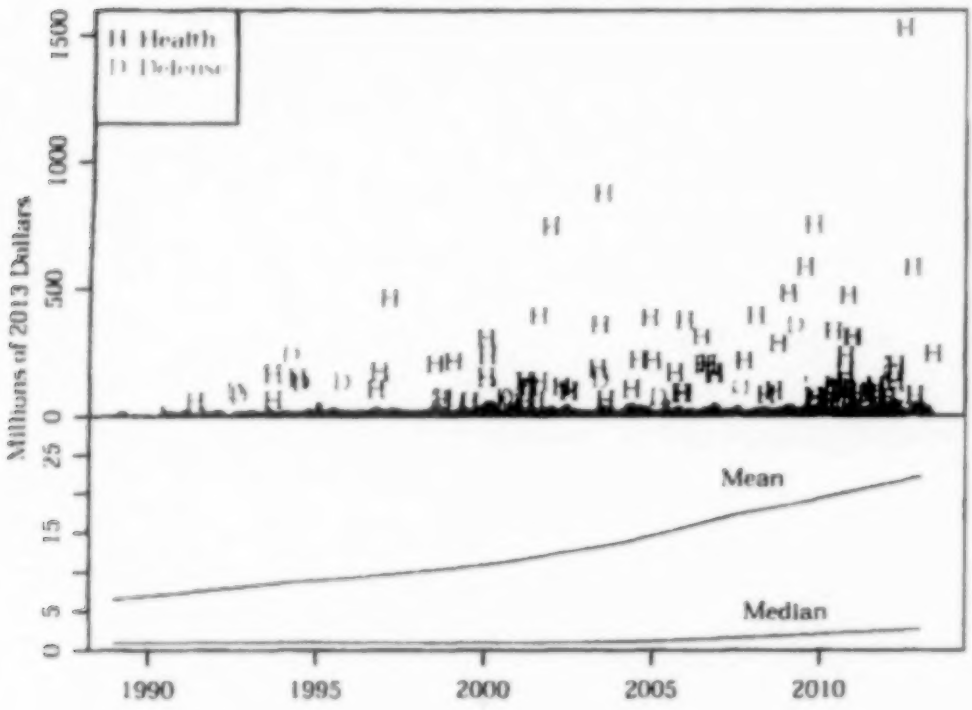
[10] Figure 2 and further analysis of *qui tam* recovery trends can be found in Engstrom, *Pathways*, *supra*, at 1958.

FIGURE 2. *QUI TAM* RECOVERIES BY CASE TYPE AND CLOSURE DATE, 1989 TO JUNE 2013



The data once more point decisively away from petitioner's and supporting *amici*'s claims about *qui tam*'s growth. While the lower stack reports that mean recoveries have roughly doubled since 2000, the upper stack's scatterplot suggests that a substantial proportion of this growth is attributable to a handful of especially large settlements of roughly $500 million or more, most of them against pharmaceutical companies.[11] Importantly, none of these large recoveries depended on implied certification claims.[12] Moreover,

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[11] They include: Abbott Laboratories ($582 million in 2012); Eli Lilly ($480 million in 2009); GlaxoSmithKline ($1.53 billion in 2012 and $471 million in 2010); and Pfizer ($750 million in 2009). More analysis can be found in Engstrom, *Pathways*, *supra*, at 1958.

[12] Five of the six cases asserted that the defendants had engaged in "off-label" marketing of drugs for uses that the Food and Drug Administration had not approved. The sixth involved a

when these large outlier cases are dropped from the sample, mean and median recoveries have remained largely stable over the period from the mid-1990s to the mid-2000s when implied certification claims began to draw judicial sanction. As with the filings analysis just presented, the overall story is relative stability, not accelerating or explosive growth, and with no obvious relationship to implied certification claims.[13]

II. IN EXERCISING ITS STATUTORY GATEKEEPER DUTIES, THE DEPARTMENT OF JUSTICE, IN CLOSE COLLABORATION WITH THE CONTRACTING AGENCY, IS A STEADY AND MERITS-FOCUSED SCREENER OF *QUI TAM* CASES

Data, not anecdote, can shed light on a second vital issue in this case: the role DOJ plays within the FCA regime via exercise of its statutory "gatekeeper" powers, including the authority to intervene in and take

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claim that the defendant sold adulterated drugs in violation of federal law.

[13] The above analyses of filings and recoveries is bolstered by a final empirical finding that is not as amenable to clean graphical presentation as Figures 1 and 2 but is nonetheless revealing. Since 1986, the average recovery per case—that is, the average number of dollars returned to the federal fisc for each *qui tam* case filed, including failed cases that produced no recovery at all—has declined only slightly and perhaps not at all. *See* Engstrom, *Pathways*, *supra*, at 1960-61. In other words, *qui tam* cases have not grown any less effective, on a per-case basis, at returning money to the federal fisc. If, as petitioner's *amici* suggest, an "army of whistleblowers, consultants, and, of course, lawyers," Chamber Br. 34, are using the implied certification theory to bring "an ever-increasing number of low-merit FCA suits," CTIA Br. 15, we would expect per-case returns to decline. The data show this is not the case.

control of *qui tam* lawsuits or dismiss or settle cases out from under relators entirely.

Petitioner and supporting *amici* contend that DOJ's exercise of these gatekeeper powers has been an unsteady and unreliable check on *qui tam* lawsuits. Indeed, petitioner goes so far as to suggest that DOJ has abused its position within the regime with respect to implied certification claims in particular. *See* Pet. Br. 53 (noting that implied certification claims in particular are "prone to abuse by the government and *qui tam* relators"). Multiple supporting *amici* also criticize DOJ for only rarely invoking its outright-dismissal powers, with one offering the conclusion that DOJ is thus "unconcerned with screening meritless cases," Chamber Br. 20 n.4.

Here again, the data offer a very different view. As shown below, DOJ has been a steady and merits-focused overseer of the regime. Moreover, while petitioner and supporting *amici* are correct that DOJ only rarely exercises its outright-dismissal powers, the data also establish that a simple declination by DOJ induces the overwhelming majority of relators to voluntarily dismiss their claims in very short order or suffer dismissal for failure to prosecute. Contrary to the view of certain *amici*, it is not the case that DOJ is "unconcerned" about meritless *qui tam* lawsuits, Chamber Br. 20 n.4. The better interpretation is that DOJ has concluded, based on long experience and with substantial empirical support, that simple declination is the superior approach.

A. Overview of DOJ's Gatekeeper Powers

The FCA gives DOJ a central role in the regime by vesting it with an array of "gatekeeper" powers

through which it oversees and controls *qui tam* lawsuits. By far the most significant of these is DOJ's power to intervene in *qui tam* actions, thus taking primary control over their prosecution.[14] DOJ enjoys other control rights as well. Even where DOJ declines to intervene, it may still dismiss or settle a *qui tam* case out from under a private relator entirely.[15]

Importantly, these formal oversight powers are not the only control tools at DOJ's disposal. DOJ can, and does, offer its views on a case by using its ability to intervene under Federal Rule of Civil Procedure 24 or

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[14] More concretely, the FCA directs *qui tam* relators to file complaints under seal, serving copies on DOJ. A 60-day seal period follows during which DOJ lawyers investigate the allegations and decide whether to: (i) terminate or settle the case; (ii) intervene and take "primary responsibility" for the litigation, if necessary limiting a relator's procedural rights; or (iii) decline to intervene and allow the relator to proceed alone. 31 U.S.C. § 3730(c)(1); *id.* § 3730(c)(2)(A)-(B) (setting forth DOJ authority to settle or terminate case out from under relator); *id.* § 3730(b)(4) (setting forth DOJ's intervention authority, including 60-day seal period); *id.* § 3730(c)(2)(C) (authorizing court to "impose limitations on [a relator's] participation" upon the government's showing that "unrestricted participation during the course of the litigation . . would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment"); *id.* § 3730(c)(3) (authorizing relator to proceed alone in the event of DOJ declination). Importantly, the bounty paid to a successful relator turns, at least in part, on the DOJ's case-election decision, with the relator keeping 15 to 25 percent where DOJ joins and 25 to 30 percent where DOJ declines. *Id.* § 3730(d)(1)-(2).

[15] In addition to its intervention and dismissal powers, DOJ must consent to any private dismissal or settlement of a *qui tam* action. *See* 31 U.S.C. § 3730(c)(2)(B). From a procedural perspective, this power is critical, since any judgment entered for or against the relator will, because she stands in the government's shoes, also preclude the government's later assertion of transactionally related claims.

to serve as an *amicus* under Federal Rule of Appellate Procedure 29. Moreover, DOJ exercises informal control over *qui tam* lawsuits via direct communication with relators. Indeed, former DOJ lawyers report that so-called "pre-election dismissals"—in which a relator voluntary dismisses a cases before DOJ even renders an election decision—typically come after DOJ has informally conveyed its intention to decline the case.[16] Thus, DOJ exercises significant control over *qui tam* lawsuits in ways that may not always be clear on the face of statistics regarding DOJ's exercise of its more formal intervention and dismissal powers.

A final key point also stands apart from statistics on DOJ intervention: Nearly all *qui tam* lawsuits allege fraud not on DOJ itself, but rather some other federal agency such as the Department of Health and Human Services or Department of Defense. This is important, for, in the civil context at least, DOJ has traditionally seen its relationship with other federal agencies, whether in discharging its duties under the FCA or in entirely different regulatory contexts, as that of attorney and client.[17] As a result, DOJ typically does not intervene, present and former DOJ lawyers report, unless the contracting agency—*i.e.*, the allegedly defrauded agency—supports the case.[18] And with good reason: An agency official's testimony that she was aware of, or even consented to, a defendant's actions

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[16] *See* Engstrom, *Public Regulation*, *supra*, at 1717 (reporting interview responses).

[17] *See* Neal Devins & Michael Herz, *The Uneasy Case for Department of Justice Control of Federal Litigation*, 5 U. Pa. J. Const. L. 558, 562 (2003).

[18] *See* Engstrom, *Public Regulation*, *supra*, at 1715 (reporting interview responses).

substantially complicates a case under the FCA's materiality and scienter provisions.

B. DOJ Intervention Patterns

Between its two main gatekeeper powers, DOJ plainly uses its intervention authority more than its dismissal authority. Indeed, prior analysis establishes that DOJ only invokes its outright-dismissal powers in as few as 1 percent of cases.[19] Given the infrequency of DOJ dismissal, Figure 3 (on the next page) focuses in on DOJ's far more common use of its intervention authority by graphing intervention patterns and rates over time and by case type.[20]

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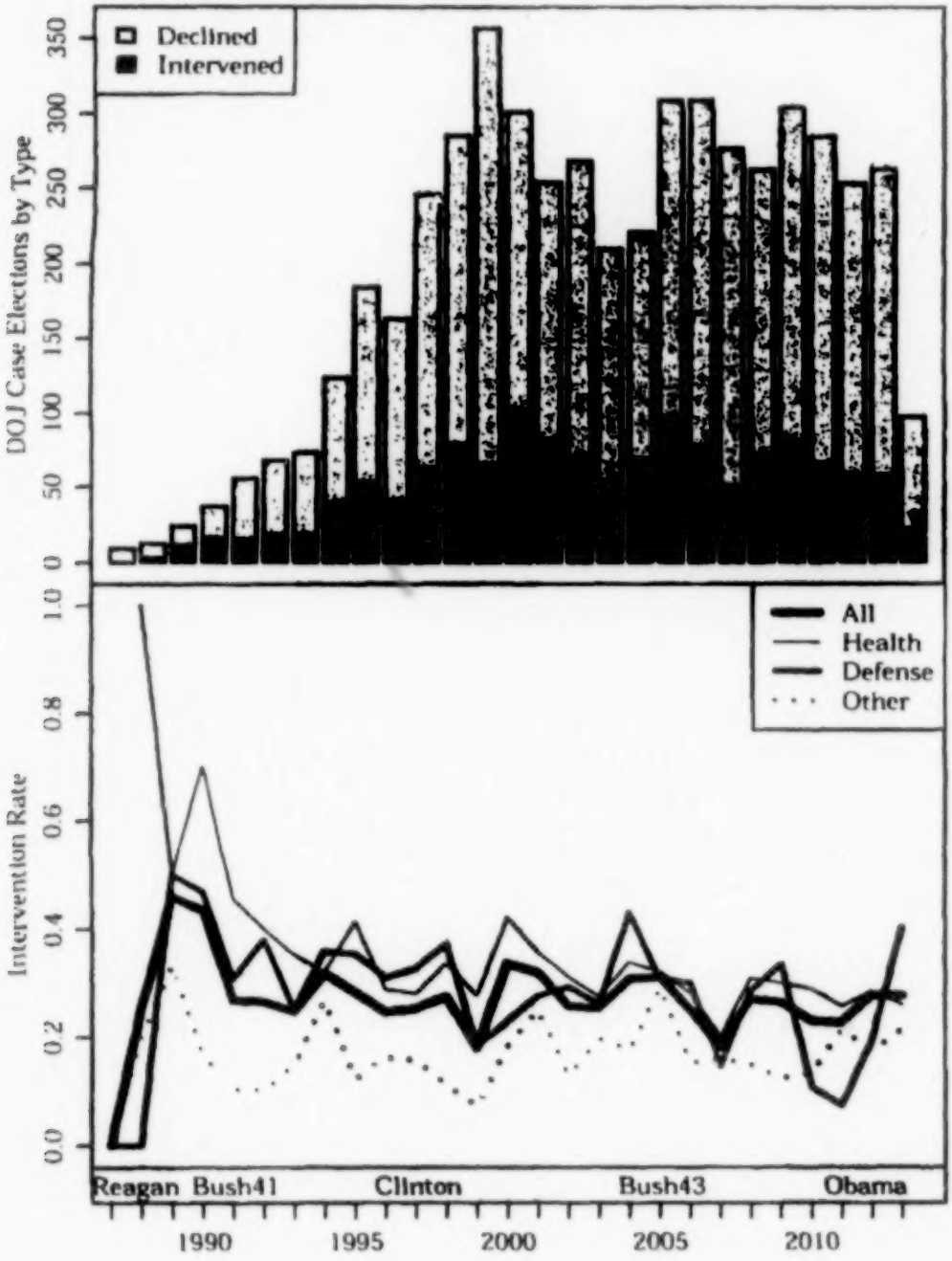
[19] For fuller analysis, see Engstrom, *Public Regulation*, *supra*, at 1717 & n.89.

[20] A version of Figure 3 and further analysis of DOJ intervention counts and rates can be found in Engstrom, *Public Regulation*, *supra*, at 1719. Note that the Figure has been updated to include data from 2012 and the first part of 2013, which were not included in the initial published analysis. Also, the fact that the updated data covers only part of 2013 explains why the top stack's tally for that year is lower than the others.

FIGURE 3: DOJ INTERVENTION COUNTS AND RATES, BY YEAR AND CASE TYPE, 1986 TO JUNE 2013



The analysis shows that DOJ intervenes roughly one-fifth to one-quarter of the time, with slightly higher intervention rates in healthcare and defense-procurement cases, and slightly lower intervention

rates in "other" case types. However, intervention rates have proven more or less stable over time, with peaks and valleys across years or case types more likely the result of sample-size limitations than anything else. Importantly, DOJ intervention patterns appear similarly variable within and across presidential administrations. While these data do not permit firm conclusions, the overall stability of the observed trends points away from the notion that DOJ makes intervention decisions on the basis of partisan-political calculation or an undue focus on particular case types. To the contrary, the stability of the measures in Figure 3 tends to support the view that DOJ makes its intervention decisions on the basis of its expert, merits-focused scrutiny of individual cases.

C. The Effect of DOJ Declination

A further inquiry of more direct relevance to DOJ's control over the regime is the effect of DOJ declination on case dispositions. Figure 4 (on the next page) begins that analysis by reporting recovery rates and amounts based on whether DOJ intervened in or declined the case.[21]

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[21] A version of Figure 4 and further analysis of *qui tam* recovery rates and amounts can be found in Engstrom, *Public Regulation*, *supra*, at 1721. However, as with Figure 3, the Figure has been updated to include data from 2012 and the first part of 2013, which were not included in the initial published analysis.

FIGURE 4: *QUI TAM* RECOVERY RATES AND MEAN AND MEDIAN RECOVERY AMOUNTS BY DOJ INTERVENTION DECISION, 1986 TO JUNE 2013

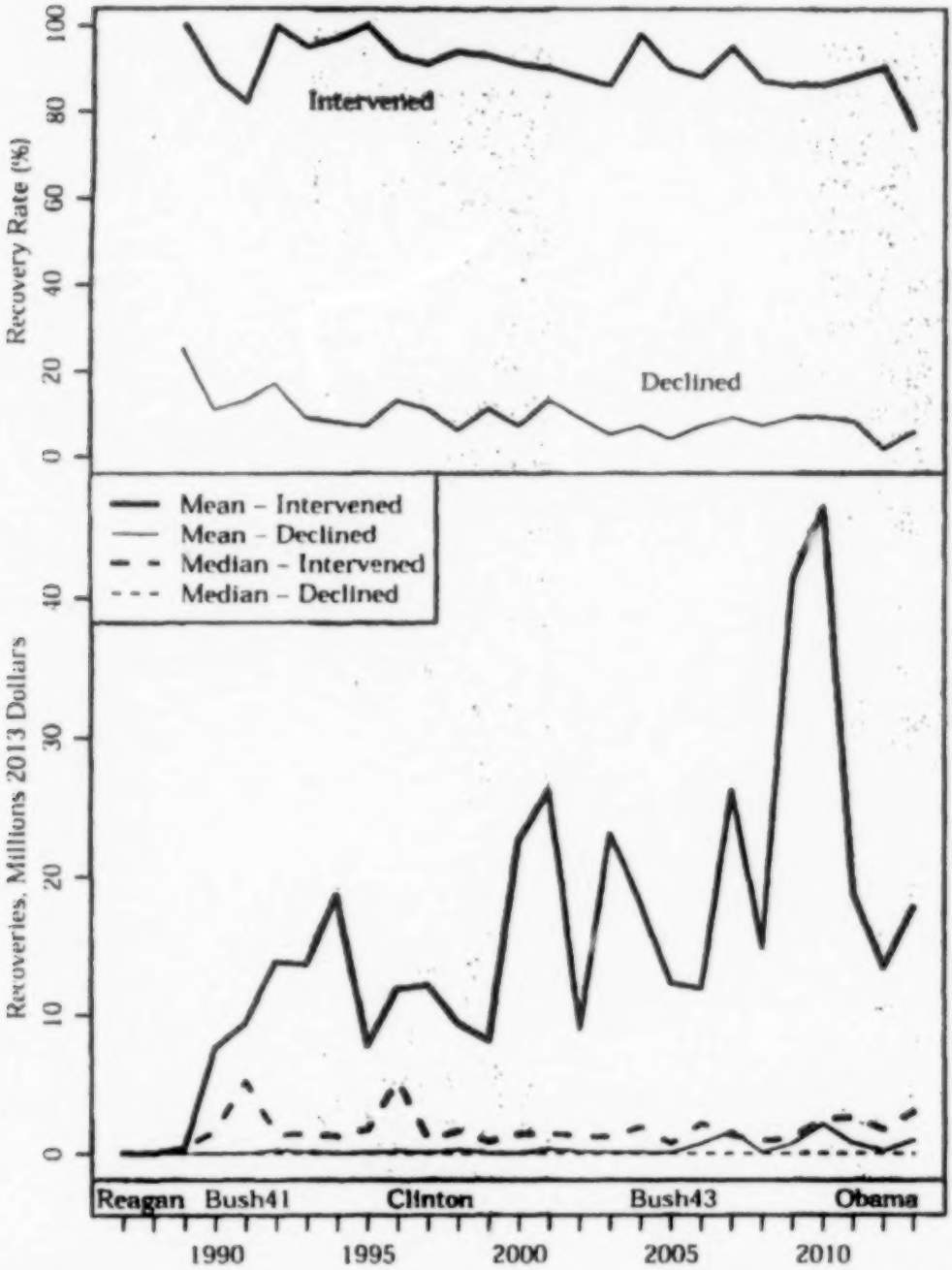

Figure 4's top stack conveys the stark reality of declined cases: Since 1986, roughly 90 percent of cases in which DOJ intervened resulted in a recovery to the

federal fisc, while only 10 percent of declined cases resulted in such a recovery. Put another way, only 10 percent of declined cases return money to the federal fisc, while only 10 percent of intervened cases *fail* to do so.

The bottom stack enriches this account by plotting mean and median recoveries for intervened and declined cases over the same time span. The plots make clear that the amount of money returned to the federal fisc in intervened cases dwarfs the amount returned in declined cases. In absolute terms, intervened cases have returned upwards of $30 billion to the federal fisc since 1986, declined cases roughly $2 billion. On a per-case basis, the disparity is equally stark: Using 2010 as a representative example, each intervened case returned, on average, $46 million to the federal fisc, each declined case an average of only $2 million. When combined with the consistent 90-versus-10-percent pattern noted above, these recovery trends demonstrate the centrality of DOJ action to the regime.[22]

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[22] Critics of the FCA regime have focused on this 90-versus-10 dynamic and the stark differences in recovery amounts in intervened and declined cases and argued that DOJ uses the weight of its authority and, in particular, the threat of a defendant's debarment from future business with the government, to ram through unfair settlements. In social scientific terms, perhaps DOJ intervention is a treatment effect (*i.e.*, DOJ litigation leverage) rather than a selection effect (*i.e.*, DOJ selection of meritorious cases). However, a regression analysis designed to get at this problem suggests otherwise, finding support for the notion that DOJ's selection of cases is substantially merits-based. *See* Engstrom, *Public Regulation*, *supra*, at 1742.

TABLE 1: DISPOSITION OF *QUI TAM* CASES WHICH DOJ DECLINED DURING 2010

Disposition of Case	Case Tally
Voluntary Dismissal (<40 days)	37
Voluntary Dismissal (>40 days), But No Litigation	21
Voluntary Dismissal After Minor Litigation (*e.g.*, complaint answer)	6
Relator Counsel Withdraws, Relator Unable to Find New Counsel	5
Relator Failure to Prosecute	21
Moderate Litigation (*e.g.*, motion to dismiss followed by voluntary or involuntary dismissal)	32
Substantial Litigation (*e.g.*, discovery, summary judgment, pre-trial), No Recovery	22
Substantial Litigation (*e.g.*, discovery, summary judgment, pre-trial), Recovery	11
Total	155

A final data-based inquiry turns away from aggregated recovery rates and amounts and provides a more granular account of the effect of DOJ declination on the disposition of specific cases. To that end, Table 1 reports findings from a hand-coded analysis of all 155 cases in which DOJ declined to intervene during the year 2010.[23] The analysis shows that nearly 60

[23] The year 2010 was chosen because it not only falls within *amicus*'s dataset, which includes cases filed between 1986 and 2013, but also ensures that adequate time has passed such that all cases have been finally litigated. If *amicus* had chosen 2013, for instance, a number of cases would not yet be closed, potentially biasing the results. Note three kinds of cases that are omitted from Table 1's analysis. First, the analysis omits two cases in which DOJ used its dismissal power, in one case because of an earlier-filed *qui tam* lawsuit asserting the same claim, in the

percent (90 out of 155) of cases which DOJ declined in 2010 resulted in virtually no litigation at all, with only a handful of these yielding even a defendant answer. Moreover, 80 percent (122 out of 155) of declined cases generated at most a motion to dismiss prior to voluntary or involuntary dismissal of the case. Importantly, among the remaining 20 percent (33 out of 155) of declined cases in which relators chose to go it alone and substantially litigated the case, one-third of relators ultimately won a recovery, thus returning money to the federal fisc despite DOJ's absence.

This more granular analysis of case dispositions in declined cases, when combined with the aggregated DOJ intervention rates and recovery amounts presented previously, provides an empirically grounded justification for DOJ's use of declination in preference to its more hard-edged dismissal authority as a way to screen out meritless cases. Indeed, it is plainly not the

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other because a *pro se* litigant had tried but failed to secure willing counsel. Second, the analysis omits nine cases in which DOJ filed a "Notice of No Election" or said it was "not intervening at this time," which is an ambiguous signal that straddles intervention and declination. Notably, the disposition of these cases does not impact the conclusions that flow from Table 1: One of the nine cases was subject to rapid (<40 days) dismissal; four produced minor or moderate litigation; one produced substantial litigation without any recovery; and three produced substantial litigation with a recovery. Third, and most importantly, the analysis omits 31 cases in which the relator voluntarily dismissed the case prior to DOJ's intervention/declination decision. As noted previously (at 14-15), former DOJ attorneys report that pre-election dismissals typically result when DOJ informally tells a relator it is planning to decline the case. Because these various cases overwhelmingly yielded dismissals without any litigation, their omission, while simplifying Table 1's presentation, also causes Table 1 to *overstate* the intensity of litigation that follows DOJ declination and thus *understate* the degree of DOJ control over *qui tam* lawsuits via its gatekeeper powers.

case, as an opposing *amicus* asserts, that DOJ is "unconcerned with screening meritless cases." *See* Chamber Br. 20 n.4. Nor is it the case, as other *amici* argue, that declination leaves "thousands" of declined cases in which relators "pursue their claims. . . unbridled by government oversight, direction, or prosecutorial discretion." *See* CTIA Br. 17; American Hospital Association Br. 21. As Table 1 shows, substantial post-declination litigation is the exception, not the rule—and, when it does occur, is often successful. The best interpretation, then, is not that DOJ is somehow asleep at the switch or, worse, abusing its statutory oversight duties. Rather, DOJ's strategy of using its intervention authority in preference to its full-dismissal power is likely optimal given ground-level litigation realities.

III. DOJ'S EXPERT EXERCISE OF ITS GATEKEEPER POWERS, BACKED WHERE NECESSARY BY JUDICIAL POLICING OF THE FCA'S MATERIALITY AND SCIENTER PROVISIONS, IS MORE FAITHFUL TO CONGRESS'S INTENT THAN PETITIONER'S BRIGHT-LINE, JUDICIALLY DEVISED RULES RESTRICTING IMPLIED CERTIFICATION CLAIMS

The empirics presented above help frame the legal issues in this case by mapping the FCA's core workings and debunking several of petitioner's and supporting *amici*'s anecdotal claims. But they also inform a further, and critically important, conclusion: Taken together, the data findings vindicate Congress's clear and repeatedly expressed judgment that case-by-case, expert DOJ gatekeeping, backed where necessary by judicial policing of the FCA's materiality and scienter provisions, provide the optimal counterbalance to the

FCA's wide scope as a broad anti-fraud tool. By contrast, petitioner's proposed bright-line rules constricting liability in implied certification cases—even where DOJ, the contracting agency, and simple common sense support the case—are unfaithful to Congress's chosen design.

A. In Crafting the Modern FCA, Congress Has Repeatedly Privileged Flexible, Case-by-Case Administrative Gatekeeping Over Blunt, Judicially-Devised Limitations on Liability

This Court has recognized that Congress designed the FCA as a broad anti-fraud tool that would "reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). Yet in crafting the modern FCA, Congress has not been unmindful of the significant challenges in structuring a regime with such broad remedial purposes. Indeed, two key themes pervade the FCA's legislative history.

First, Congress has repeatedly walked a tightrope between a pair of classic challenges regulatory architects face in choosing among public and private enforcement mechanisms. On the one hand, profit-seeking private enforcers, left to their own devices, can be overzealous, enforcing even when the social costs of doing so outstrip the benefits.[24] But purely public enforcement is not perfect, either. Public resources are limited, and public agencies and prosecutor's offices

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[24] *See, e.g.*, Steven Shavell, *The Fundamental Divergence Between the Private and the Social Motive to Use the Legal System*, 26 J. Legal Stud. 575, 578 (1997).

can suffer from public-sector inefficiencies, organizational inertia, or even "capture" by regulated interests.[25]

Mindful of these challenges, Congress's ingenious solution has been to construct a carefully balanced hybrid of public and private enforcement in which each type of actor, public and private, complements but also disciplines the other. For instance, by arming *qui tam* relators with a right of action and a cut of any (trebled) recovery, Congress deputized an army of "private attorneys general" to surface information about fraud that the government could never discover on its own. *See, e.g.*, S. Rep. No. 110-507, at 6 (2008) (noting the "critical role that *qui tam* relators play" in surfacing information about fraud that would otherwise "go unnoticed"). Congress also expressly contemplated that relators who choose to go it alone after DOJ declination would "prod[]" and "nudg[e]" an overburdened or politicized bureaucracy. *False Claims Act Amendments: Hearings Before the Subcomm. on Admin. Law & Governmental Relations of the H. Comm. on the Judiciary*, 99th Cong. 174 (1986) (statement of Rep. Howard Berman); *see also* 132 Cong. Rec. 22,340 (1986) (statement of Rep. Berkley Bedell) ("[T]he Justice Department has neither the political will nor the resources to always enforce all of the laws.").

At the same time, Congress also gave DOJ substantial control rights over *qui tam* lawsuits, including, as noted (*supra* at 13 n.14), the power to intervene in and take control of *qui tam* suits or to settle or dismiss them out from under relators entirely. Importantly, Congress also ensured that DOJ's exercise

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[25] *See, e.g.*, Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 Harv. L. Rev. 1193, 1226, 1298 (1982).

of those control rights would be subject to only minimal judicial review.[26] In so doing, Congress unmistakably made DOJ the primary, and often the final, counterbalance to the private, profit-driven side of the FCA regime.

A second theme that pervades the legislative history is that Congress, in calibrating the FCA's unique public-private hybrid structure, has repeatedly privileged flexible, case-by-case mechanisms of control over rigid, bright-line rules constricting liability. DOJ's various gatekeeper powers, the regime's centerpiece, are a case in point. Their exercise by DOJ demands careful, context-sensitive inquiry performed in collaboration with the contracting agency—not *ex ante*, across-the-board limitations generated by courts from afar.[27]

Moreover, where Congress has sought to arm courts with tools to check meritless *qui tam* lawsuits as a backstop to DOJ gatekeeping, it has done so via flexible tests rather than bright-line rules. For instance, in adding a scienter requirement to the FCA in 1986, Congress rejected a "rigid definition" of knowledge because of the "wide variance of circumstances under

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[26] For instance, Congress could have subjected DOJ declination decisions to judicial review but did not. Moreover, Congress's decision in § 3730(c)(2) to grant a relator facing DOJ dismissal "an opportunity for hearing" has been interpreted by courts to require review for only minimal rationality. *See, e.g., United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (requiring that DOJ show only a "rational relation" between dismissal and a valid government purpose).

[27] As noted below (at 28), Congress's design thus embodies faith in the expert, context-sensitive exercise of agency discretion that underpins this Court's administrative law jurisprudence. *See Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 864-65 (1984).

which the Government funds its programs and the correlating variance in sophistication of program recipients." S. Rep. No. 99-345, at 20 (1986). Congress's addition of a "materiality" element in its 2009 FERA amendments armed courts with a similarly flexible tool as a backstop against meritless claims. *See* 31 U.S.C. § 3729(b)(4); S. Rep. No. 111-10, at 12 (2009) (explaining the new "material" term).

By contrast, Congress has repeatedly and soundly rejected bright-line, judicially devised rules contracting FCA liability. Most notably, the 1986 amendments, which increased monetary awards and adopted a lower burden of proof, were also "aimed at correcting restrictive interpretations of the act's liability standard." S. Rep. No. 99-345, at 4 (1986). Among these were narrow readings of the FCA that, by categorically barring claims whenever the government had at least some knowledge of the misconduct, discouraged relators with valuable, first-hand information about wrongdoing from coming forward at all. *See United States ex rel. Springfield Terminal Ry. Co. v Quinn*, 14 F.3d 645, 650 (D.C. Cir. 1994) (recounting the legislative history and cases).

Likewise, Congress enacted FERA in 2009 in large part "to remove judicially-created limitations and qualifications which ha[d] undermined" FCA enforcement. H.R. Rep. No. 111-97, at 2, 5 (2009); *see also* S. Rep. No. 111-10, at 4, 10 (2009). The main culprits Congress identified were this Court's decision in *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2012), as well as *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004), in which the D.C. Circuit interpreted the FCA's "presentment clause" to categorically bar suit where a subcontractor submitted a false claim to a contractor rather than the

government itself. *Id.* at 498; S. Rep. No. 111-10, at 10 (2009) (noting particular purpose of overruling *Allison Engine* and *Totten*).

B. Petitioner's Proposed Bright-Line Limitations on FCA Liability Cannot Be Reconciled with Congress's Chosen Design

Petitioner asks this Court to adopt a bright-line rule foreclosing implied certification liability entirely or, failing that, an equally bright-line requirement that the government expressly condition payment on compliance with even the most self-evidently material statutory or regulatory provisions. Pet. Br. 28, 41. Neither line-drawing, as respondents convincingly argue, finds textual support in the FCA. *See* Resp. Br. 22-32, 41-46. But petitioner's proposed "solutions" fail for a further reason: They violate both of the above tenets of the FCA's legislative history.

First, a bright-line judicial rule foreclosing or severely limiting implied certification liability would disrupt Congress's careful counterbalancing of the public and private sides of the regime. As just one example, a bright-line rule would short-circuit Congress's carefully calibrated public-private hybrid by preventing many relators from coming forward at all, thus impairing DOJ's ability to shape the flow of information that relators bring forward.[28]

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[28] Petitioners' proposed bright-line rules would also prevent relators from playing a salutary agency-forcing role in instances where an agency that has self-evidently been defrauded refuses to invoke available remedies or even opposes DOJ intervention, either because it hopes to cover up lax oversight or because it has fallen under the influence of a powerful industry. *See* Engstrom, *Public Regulation*, *supra*, at 1715 (noting the view of a former

Second, a bright-line rule would contravene Congress's repeated efforts to construct a highly flexible, administrative bulwark—not a rigid, judicially devised one—against unjustified FCA liability. For instance, petitioner's condition-of-payment rule would put courts, not an expert agency, in the role of working through complex statutory and regulatory provisions in search of magic words that rise to the level of an express condition of payment. Worse, a court wielding petitioner's bright-line rule would perform this inquiry without taking any account of the course of conduct between the contracting agency and a defendant.

In other contexts, this Court extends formal deference to an agency's interpretation of statutes it administers, *Chevron*, 467 U.S. at 864, and even heavier deference to an agency's interpretation of its own regulations, *Auer v. Robbins*, 519 U.S. 452 (1997); *Decker v. Nw. Envtl. Def. Ctr.*, 133 S. Ct. 1326 (2013) (re-affirming *Auer*'s vitality). In the latter context, this Court has deferred based on its sound judgment that agencies are best-positioned to gauge the significance and meaning of their own regulations. *Auer*, 519 U.S. at 461. In making DOJ, in consultation with the contracting agency, the primary bulwark against unjustified FCA liability, Congress followed a similar logic.

Petitioner appears to take the opposite position in arguing that the voluminous regulatory backdrop in public programs such as Medicare, coupled with the fact-intensive nature of the FCA's materiality and scienter inquiries, necessitate a bright-line rule limiting liability. *See* Pet. Br. 53-56. But the answer to lengthy,

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DOJ attorney that defrauded agencies sometimes refuse to enforce and even oppose DOJ intervention in order to cover up "lax oversight or other mistakes").

technocratic regulations is not a categorical rule foreclosing liability across the board. The better solution is to entrust DOJ, in close collaboration with the contracting agency, with the power to consider the regulatory framework and the course of conduct between the agency and contractor and decide, within the constraints of the FCA's scienter and materiality provisions, whether a defendant's conduct justifies further enforcement effort.

Finally, the soundness of Congress's decision to make DOJ the primary bulwark against meritless FCA cases is made still clearer when one considers the stark consequences of petitioner's proposed limitations on FCA liability. As respondents note, petitioner's artificial, bright-line rule would bind even where the fraudulent nature of the defendant's actions are self-evident to any reasonable person. *See* Resp. Br. 46-49. Security firms whose guards cannot shoot, pharmaceutical companies that knowingly sell dangerous adulterated drugs, and, as in the instant case, healthcare providers that seek reimbursement for professional services performed by non-professionals: These are only a sampling of cases that would evade FCA liability under petitioner's proposed rules.

In modernizing the FCA, Congress did not intend to replace agency-centered scrutiny of case merit with an artificial, bright-line, judicially devised rule foreclosing or severely limiting liability in situations like these. To suggest otherwise is to ignore the uniqueness of the modern FCA's public-private hybrid structure and the careful balance Congress struck in crafting it. Deference to Congress's faith in DOJ's expert and steady exercise of its gatekeeper powers should thus guide this Court's decision.

CONCLUSION

The Court should affirm the First Circuit's decision below.

Respectfully submitted,

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March 3, 2016